MAY 0 1 2014
K132857

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PACIFIC MEDICO

510(k) Summary

Sumitter/510(k) Holder
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Registration Number: 10028261

Contact Person: Yoshio Toyama

Date of Preparation: March 20, 2014

Manufacturing Facility
Pacific Denshi Co., Ltd.
650-6, Okaisshiki, Sizuoka, 410-0012, Japan
Registration #:3007584704

Device Name
Classification Reference: 21 CFR 868.5450
Product Code: BTT
Device Trade Name: Humidifier Heater Base PMH7000PLUS/PMH7000
Classification Name: Respiratory Gas Humidifier
Classification: Class II

Predicate Device
The predicate device is Humidifier Heater Base, PMH7000 with 510(k) number, K080149 and the concurrence date December 18, 2008.

Device Description
The Humidifier Heater Base, PMH7000PLUS/PMH7000 is a humidifier incorporating with ventilator and provides respiratory humidification through patient breathing circuit for adult at hospital and home.

Humidifier Heater Base, PMH7000PLUS/PMH7000 was designed to comply with applicable portions of the following standards.

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IEC 60601-1	Medical Electrical Equipment – General Requirements
IEC 60601-1-2	Electromagnetic Compatibility – Requirements and Tests
ISO 8185	Humidifiers for Medical Use
ISO 14971	Medical Devices

This heater base features a dual temperature servo control system which regulates the temperature of the gas delivered to the patient and the gas at outlet of humidifying chamber. It continuously monitors temperatures by a dual temperature probe. The heater base warms and humidifies the gas through the humidifier chamber and in addition a heater wire in the patient breathing circuit further controls same gas temperature. The operator is allowed to set the temperature of two locations; temperature of the chamber outlet gas and the gas immediately before delivered to the patient.

The Humidifier Heater Base PMH7000PLUS/PMH7000 is equipped with alarms which activate audible and visual indicators to alert the operator of adverse conditions. Alarms are provided for high and low airway temperature, high and low chamber outlet temperature, temperature probe disconnect or fault condition, heater wire fault connection, and the light identifies the area of alarm.

The Humidifier Heater Base PMH7000PLUS/PMH7000 includes several safety features such as prevention of excessive heating which can be harmful to the patient or can cause damage to the heater base itself. To ensure patient safety, the heater base will shut down under any alarm conditions if it continues for 10 minutes.

The Humidifier Heater Base are available in two models; PMH7000PLUS and PMH7000. PMH7000PLUS/PMH7000 has both inspiratory and expiratory heater wires for use in the inspiratory and expiratory limbs of breathing circuit. The use of the expiratory heater wire with PMH7000PLUS/PMH7000 is to control humidity in the expiratory limb and to reduce moisture returned to the ventilator.

The materials used have not been changed.

Description of Device Modification
The subject device has the same technological characteristics and indications for use, material composition, intended use as predicate; the hardware, software, and mechanical aspects of Humidifier Heater Base, PMH7000PLUS/PMH7000 have been updated to current technology equivalent to the cleared device (Humidifier Heater Base, PMH7000, K080149 dated December 18, 2008) as described below. The subject device is substantially equivalent to the predicate device.

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Humidifier Heater Base, PMH7000PLUS/PMH7000 are modified version of Humidifier Heater Base, PMH7000.

The modification is to change the front and side panel design in order to realize the easy maneuverability and, and to change the interface for heater wire connector in order to facilitate easy and simple connectivity.

Modifications which have been made are described below.

PMH7000PLUS:
1) changing the front and side panel design
2) changing the interface connector for heater wire
3) improving the maneuverability.

PMH7000:
1) changing the front and side panel design
2) changing the interface connector for heater wire

Because of the improvements of the maneuverability from predicate device of PMH7000, the upgraded model of PMH7000 is added under the name of PMH7000PLUS. The purpose of adding this name of PMH7000PLUS is to identify the differentiation from the predicate device.

Intended Use
The Humidifier Heater Base PMH7000PLUS/PMH7000 is intended to add moisture and to warm the breathing gasses for administration to a patient.

The Humidifier Heater Base, PMH7000PLUS/PMH7000 is intended for use on adult at hospital and home.

The intended use has not been changed.

Technological Characteristics
The Technological Characteristics of Humidifier Heater Base PMH7000PLUS/ PMH7000 are equivalent to the predicate devices Humidifier Heater Base PMH7000 (available in two models, the PMH7000D and the PMH7000S). PMH7000PLUS/PMH7000 are equivalent to the PMH7000 in terms of: type (heated Passover humidification), configuration (chamber, heated wire breathing circuits, dual –sensor temperature probe), power usage (same heater system ratings),

performance (same temperature and humidity output), control method (electronic and PID algorithm microprocessor), and uses equivalent materials and some common components.

Non Clinical Tests

Non-clinical testing of Humidifier Heater Base PMH7000PLUS/ PMH7000 has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance capacity and accuracy.
PMH7000PLUS/ PMH7000 meets the requirements of the IEC 60601-1 and IEC 60601-1-2 electro medical and EMC standards, and the relevant USA deviations to these in ANSI/AAMI ES60601-1. It complies with performance and safety requirements of the ISO 8185 particular standard for Humidification Systems.

Substantial Equivalence

The modified PMH7000PLUS/PMH7000 have the following similarities to those which previously received 510(k) concurrence (PMH7000).

- have the same intended use,
- use the same operating principle,
- incorporate the same basic humidifier design,
- have the same shelf life, and
- packaged using the same materials and process.

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. This is to demonstrate that Pacific Medico PMH7000PLUS/PMH7000 Humidifier Heater Base for respiratory therapy (heater base) is substantially equivalent to the predicate device.

Conclusion

The testing carried out for Humidifier Heater Base PMH7000PLUS/PMH7000 indicates that it meets design and performance functional requirements. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from the particular standard for humidification systems.

This information indicates that Humidifier Heater Base PMH7000PLUS/PMH7000 is substantially equivalent to the predicate devices.

1) The modification does not affect the intended use or alter the fundamental scientific technology.

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2) Based on the results of the comparison and reproducibility studies described in this 510(k) submission, it is concluded that the Humidifier Heater Base, PMH7000PLUS/PMH7000 is equivalent to the predicate device as an aid for mitigation of dryness of airway.
3) Under the above technological comparison, discussion on substantial equivalence, it is demonstrated that the PMH7000PLUS/PMH7000 is equivalent to the predicate device.
4) It is determined that the Performance Testing – Clinical is not required because of the above comparison.
5) Verification and validation testing have been performed which demonstrate that PMH7000PLUS/PMH7000 function as intended and is substantially equivalent to the predicate devices for the intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

Pacific Medico Co., LTD.
Mr. Yoshio Toyama, General Manager
Regulatory Affairs, Product Development Department
2-6-4 Hongo, Bunkyo-ku
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Re: K132857
Trade/Device Name: Humidifier Heater Base PMH7000PLUS/PMH7000
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Toyama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

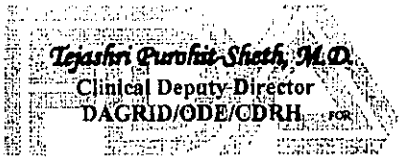
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132857

Device Name
Humidifier Heater Base PMH7000PLUS/PMH7000

Indications for Use *(Describe)*
The Humidifier Heater Base PMH7000PLUS/PMH7000 is intended to add moisture and to warm the breathing gases for administration to the patient.

The Humidifier Heater Base, PMH7000PLUS/PMH7000 is intended for use on adult at hospital and home.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2014.05.05
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